

REMARKS

Applicant acknowledges receipt of the Final Office Action mailed April 11, 2011.

In the Final Office Action¹, the Examiner rejected claims 29, 30, 41-45, 48-50, 55, 58-62, 64, and 65 under 35 U.S.C. § 103(a) as being unpatentable over *Lindsay et al.* (U.S. Patent No. 4,433,971) in view of *Verkaart et al.* (U.S. Patent No. 5,707,431); rejected claims 31-33, 56, and 57 under 35 U.S.C. § 103(a) as being unpatentable over *Lindsay* in view of *Verkaart*, and further in view of *Buckberg* ("*Buckberg* '469") (U.S. Patent No. 5,011,469); rejected claims 39 and 40 under 35 U.S.C. § 103(a) as being unpatentable over *Lindsay* in view of *Verkaart*, and further in view of *Strauss et al.* (U.S. Patent No. 5,837,905); rejected claims 46 and 47 under 35 U.S.C. § 103(a) as being unpatentable over *Lindsay* in view of *Verkaart*, and further in view of *Bringham et al.* (U.S. Patent No. 4,698,207); rejected claims 51 and 63 under 35 U.S.C. § 103(a) as being unpatentable over *Lindsay* in view of *Verkaart*, and further in view of *Buckberg* ("*Buckberg* '191") (U.S. Patent No. 5,643,191); and rejected claims 34-38 under 35 U.S.C. § 103(a) as being unpatentable over *Lindsay* in view of *Verkaart*, and further in view of *Buckberg* '469 and *Strauss*.

By this Amendment, Applicant amends claims 29 and 57-65. Claims 29-65 remain pending. Of these claims, claims 29 and 57-65 are the pending independent claims.

The originally-filed specification, claims, abstract, and drawings fully support amended claims 29 and 57-65. No new matter has been introduced.

¹ The Final Office Action contains a number of statements reflecting characterizations of the related art and the claims. Regardless of whether any such statement is identified herein, Applicant declines to automatically subscribe to any statement or characterization in the Final Office Action.

Applicant traverses the rejections above and respectfully requests reconsideration for at least the reasons that follow.

I. 35 U.S.C. § 103(a) REJECTIONS

Applicant traverses the rejection of claims 29, 30, 41-45, 48-50, 55, 58-62, 64, and 65 under 35 U.S.C. § 103(a) as being unpatentable over *Lindsay* in view of *Verkaart*. Applicant respectfully disagrees with the Examiner's arguments and conclusions and submits that amended independent claims 29, 58-62, 64, and 65 patentably distinguish over *Lindsay* and *Verkaart* at least for the reasons described below.

The key to supporting any rejection under 35 U.S.C. § 103 is the clear articulation of the reason(s) why the claimed invention would have been obvious. See M.P.E.P. § 2142, 8th Ed., Rev. 7 (July 2008). Such an analysis should be made explicit and cannot be premised upon mere conclusory statements. See id. "A conclusion of obviousness requires that the reference(s) relied upon be enabling in that it put the public in possession of the claimed invention." M.P.E.P. § 2145. Furthermore, "[t]he mere fact that references can be combined or modified does not render the resultant combination obvious unless the results would have been predictable to one of ordinary skill in the art" at the time the invention was made. M.P.E.P. § 2143.01(III), internal citation omitted. Moreover, "[i]n determining the differences between the prior art and the claims, the question under 35 U.S.C. § 103 is not whether the differences themselves would have been obvious, but whether the claimed invention as a whole would have been obvious." M.P.E.P. § 2141.02(I), internal citations omitted (emphasis in original).

"[T]he framework for the objective analysis for determining obviousness under 35 U.S.C. 103 is stated in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966). . . . The factual inquiries . . . [include determining the scope and content of the prior art and] . . . [a]scertaining the differences between the claimed invention and the prior art." M.P.E.P. § 2141(II). "Office personnel must explain why the difference(s) between the prior art and the claimed invention would have been obvious to one of ordinary skill in the art." M.P.E.P. § 2141(III).

Amended independent claim 29, and similarly amended independent claims 58-62, 64, and 65, recites a fluid distribution module for causing and monitoring a circulation of fluids from and to a patient through an extracorporeal blood treatment device, comprising: "a degassing device comprising: a first chamber having an inlet for a liquid; [and] a second chamber having a lid including a vent, a hydrophobic membrane closing an opening of the second chamber within the lid, and an outlet for discharging the liquid, the hydrophobic membrane being allowed to deform under pressure until the membrane contacts a top wall of the lid" (emphases added).

Lindsay discloses a bubble trap for a cardioplegia system in which cardioplegia medication or a mixture of arterial blood and medication is delivered to the heart of a patient undergoing open heart surgery which includes a bubble trap in conjunction with the delivery system which separates air from the arterial flow and provides visual indication of an increase of air in the system, together with a flow means for lengthening the path of flow through the trap to achieve maximum separation of air from the arterial flow. (*Lindsay*, Abstract).

The Examiner concedes, however, that *Lindsay* "does not specifically teach that

the hydrophobic membrane is disposed within the lid portion, such that it closes the opening at the upper portion of the second chamber.” (*Final Office Action*, p. 3, ll. 16-18).

In order to cure the deficiencies of *Lindsay*, the Examiner relies on *Verkaart* and alleges “*Verkaart* teaches that the top portion of the system comprises a lid portion 18 comprising a vent 6 and a flexible hydrophobic membrane 16 that is disposed within the lid portion, such that it closes the upper opening of the second chamber. (*Final Office Action*, p. 3, line 22 - p. 4, line 3). Applicant respectfully disagrees.

Verkaart fails to teach or suggest a hydrophobic membrane that can deform under positive pressure until it abuts against a top wall of a lid of a second chamber. *Verkaart* merely discloses that the hydrophobic membrane 16 is mounted in a two-part cap 18. *Verkaart* further states that “[i]n the normal situation, gas passing through membrane 16 generates enough pressure to lift upper surface 20 from seat 22 to allow the gas to exit the device.” (*Verkaart*, col. 2, ll. 59-62). There is no question, however that *Verkaart* does not disclose that the hydrophobic membrane 16 is allowed to deform under pressure until it contacts the upper surface 20 of the two-part cap 18.

As explained above, the elements of independent claims 29, 58-62, 64, and 65 are neither taught nor suggested by the cited references. Consequently, in the Final Office Action, the Examiner has neither properly determined the scope and content of the prior art, nor properly ascertained the differences between the prior art and the claims. Accordingly, no sufficient reason has been clearly articulated as to why the claims would have been obvious to one of ordinary skill in view of the prior art. Therefore, a *prima facie* case of obviousness has not been established for independent

claims 29, 58-62, 64, and 65 and these claims are allowable over the cited references.

Claims 30, 41-45, 48-50, and 55 are also allowable over *Lindsay* and *Verkaart* due at least to their dependence from allowable independent claim 29, and due to their additional recitations of novel subject matter. Applicant therefore requests that the rejection of claims 29, 30, 41-45, 48-50, 55, 58-62, 64, and 65 under 35 U.S.C. § 103(a) be withdrawn.

Applicant also traverses the rejection of claims 31-33, 56, and 57 under 35 U.S.C. § 103(a) as being unpatentable over *Lindsay* in view of *Verkaart*, and further in view of *Buckberg* '469. Applicant respectfully disagrees with the Examiner's arguments and conclusions and submits that amended independent claim 57 patentably distinguishes over *Lindsay*, *Verkaart*, and *Buckberg* '469 at least for the reasons described below.

Amended independent claim 57 recites a fluid distribution module for causing and monitoring a circulation of fluids from and to a patient through an extracorporeal blood treatment device, comprising: "a degassing device comprising: a first chamber having an inlet for a liquid; [and] a second chamber having a lid including a vent, a hydrophobic membrane closing an opening of the second chamber within the lid, and an outlet for discharging the liquid, the hydrophobic membrane being allowed to deform under pressure until the membrane contacts a top wall of the lid" (emphases added).

As discussed above, *Lindsay* and *Verkaart* fail to teach or suggest a fluid distribution module for causing and monitoring a circulation of fluids from and to a patient through an extracorporeal blood treatment device, comprising: "a degassing

device comprising: a first chamber having an inlet for a liquid; [and] a second chamber having a lid including a vent, a hydrophobic membrane closing an opening of the second chamber within the lid, and an outlet for discharging the liquid, the hydrophobic membrane being allowed to deform under pressure until the membrane contacts a top wall of the lid" (emphases added). The Examiner further concedes that "Lindsay . . . is silent regarding whether the withdrawal line comprises pumps on *both sides* of the oxygenator (such that the withdrawal conduit comprises a fourth conduit extending from the patient access to a pump, and a fifth conduit that extends from said pump to said oxygenator)." (*Final Office Action*, p. 6, ¶12).

In order to cure the deficiencies of *Lindsay* and *Verkaart*, the Examiner relies on *Buckberg '469* and contends that "Buckberg . . . teaches an extracorporeal cardioplegia delivery system for oxygenating blood comprising a withdrawal conduit (29, 40), a withdrawal pump 18, an oxygenator 20, a cardioplegia pump 24, and an infusion lumen . . ." (*Final Office Action*, p. 6, line 21- p. 7, line 3).

Such teaching, even if present in *Buckberg '469*, which Applicant does not necessarily concede, however, fails to teach or suggest at least a fluid distribution module, comprising: "a degassing device comprising . . . a second chamber having a lid including a vent, a hydrophobic membrane closing an opening of the second chamber within the lid, and an outlet for discharging the liquid, the hydrophobic membrane being allowed to deform under pressure until the membrane contacts a top wall of the lid" (emphases added), as recited in amended independent claim 57.

As explained above, the elements of independent claim 57 are neither taught nor suggested by the cited references. Consequently, in the Final Office Action, the Examiner has neither properly determined the scope and content of the prior art, nor properly ascertained the differences between the prior art and the claim. Accordingly, no sufficient reason has been clearly articulated as to why the claim would have been obvious to one of ordinary skill in view of the prior art. Therefore, a *prima facie* case of obviousness has not been established for independent claim 57 and this claim is allowable over the cited references.

Claims 31-33 and 56 are also allowable over *Lindsay*, *Verkaart*, and *Buckberg '469* due at least to their dependence from allowable independent claim 29, and due to their additional recitations of novel subject matter. Applicant therefore requests that the rejection of claims 31-33, 56, and 57 under 35 U.S.C. § 103(a) be withdrawn.

In addition, Applicant traverses the rejection of claims 51 and 63 under 35 U.S.C. § 103(a) as being unpatentable over *Lindsay* in view of *Verkaart*, and further in view of *Buckberg '191*. Applicant respectfully disagrees with the Examiner's arguments and conclusions and submits that amended independent claim 63 patentably distinguishes over *Lindsay*, *Verkaart*, and *Buckberg '191* at least for the reasons described below.

Amended independent claim 63 recites a fluid distribution module for causing and monitoring a circulation of fluids from and to a patient through an extracorporeal blood treatment device, comprising: "a degassing device comprising: a first chamber having an inlet for a liquid; [and] a second chamber having a lid including a vent, a hydrophobic membrane closing an opening of the second chamber within the lid, and an

outlet for discharging the liquid, the hydrophobic membrane being allowed to deform under pressure until the membrane contacts a top wall of the lid" (emphases added).

As discussed above, *Lindsay* and *Verkaart* fail to teach or suggest a fluid distribution module for causing and monitoring a circulation of fluids from and to a patient through an extracorporeal blood treatment device, comprising: "a degassing device comprising: a first chamber having an inlet for a liquid; [and] a second chamber having a lid including a vent, a hydrophobic membrane closing an opening of the second chamber within the lid, and an outlet for discharging the liquid, the hydrophobic membrane being allowed to deform under pressure until the membrane contacts a top wall of the lid" (emphases added). The Examiner further concedes that "*Lindsay* and *Verkaart* . . . do not specifically teach that the hydrophobic membrane is disposed adjacent the accumulation of gas bubbles." (*Final Office Action*, p. 9, para. 16).

In order to cure the deficiencies of *Lindsay*, the Examiner relies on *Buckberg '191* and contends that "*Buckberg* . . . teaches a cardioplegia treatment system comprising a degassing chamber for removing gas from blood. Blood passes into a first chamber, then rises into a second chamber . . ." (*Final Office Action*, p. 9, ll. 19-21).

Such teaching, even if present in *Buckberg '191*, which Applicant does not necessarily concede, however, fails to teach or suggest at least a fluid distribution module, comprising: "a degassing device comprising . . . a second chamber having a lid including a vent, a hydrophobic membrane closing an opening of the second chamber within the lid, and an outlet for discharging the liquid, the hydrophobic membrane being allowed to deform under pressure until the membrane contacts a top wall of the lid" (emphases added), as recited in amended independent claim 63.

As explained above, the elements of independent claim 63 are neither taught nor suggested by the cited references. Consequently, in the Final Office Action, the Examiner has neither properly determined the scope and content of the prior art, nor properly ascertained the differences between the prior art and the claim. Accordingly, no sufficient reason has been clearly articulated as to why the claim would have been obvious to one of ordinary skill in view of the prior art. Therefore, a *prima facie* case of obviousness has not been established for independent claim 63 and this claim is allowable over the cited references.

Claim 51 is also allowable over *Lindsay*, *Verkaart*, and *Buckberg '191* due at least to its dependence from allowable independent claim 29, and due to its additional recitation of novel subject matter. Applicant therefore requests that the rejection of claims 51 and 63 under 35 U.S.C. § 103(a) be withdrawn.

Claims 39 and 40 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over *Lindsay* in view of *Verkaart*, and further in view of *Strauss*; claims 46 and 47 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over *Lindsay* in view of *Verkaart*, and further in view of *Bringham*; and claims 34-38 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over *Lindsay* in view of *Verkaart*, and further in view of *Buckberg '469* and *Strauss*. Applicant respectfully traverses these rejections and requests that the Examiner withdraw the rejections and allow the claims.

As noted previously, *Lindsay* and *Verkaart* do not disclose or suggest a fluid distribution module, comprising: "a degassing device comprising . . . a second chamber having a lid including a vent, a hydrophobic membrane closing an opening of the second chamber within the lid, and an outlet for discharging the liquid, the hydrophobic

membrane being allowed to deform under pressure until the membrane contacts a top wall of the lid" (emphases added), as recited in amended independent claim 29.

Strauss, Bringham, and Buckberg '469 also do not remedy the deficiencies of *Lindsay* and *Verkaart*.

With respect to *Strauss*, the Examiner asserts that "Strauss et al . . . teaches a unitary cardioplegia flow control and monitoring cassette comprising a plurality of predefined flow paths having a plurality of sockets onto which tubing segments are mounted" (*Final Office Action*, p. 8, ll. 1-4); with respect to *Bringham*, the Examiner alleges that "Bringham et al . . . teaches an integrated oxygenator and gas removal device wherein blood is inserted tangentially around the inlet to the oxygenator" (*Id.* at p. 9, ll. 4-6); and with respect to *Strauss*, the Examiner asserts that "Strauss teaches a unitary cardioplegia flow control and monitoring cassette comprising a plurality of predefined flow paths having pressure-sensing cells . . . attached thereto" (*Id.* at p. 10, ll. 18-20). Such teachings, even if present in *Strauss, Bringham, and Buckberg '469*, which Applicant does not necessarily concede, however, fail to teach or suggest a fluid distribution module, comprising: "a degassing device comprising . . . a second chamber having a lid including a vent, a hydrophobic membrane closing an opening of the second chamber within the lid, and an outlet for discharging the liquid, the hydrophobic membrane being allowed to deform under pressure until the membrane contacts a top wall of the lid" (emphases added), as recited in allowable independent claim 29.

Moreover, claims 34-40, 46, and 47 depend from independent claim 29 and require all elements thereof. As explained above, the elements of independent claim 29 are neither taught nor suggested by the cited references. In addition, in the Final Office

Action, the Examiner has neither properly determined the scope and content of the prior art nor ascertained the differences between the prior art and these claims. No reason has been clearly articulated as to why these claims would have been obvious to one of ordinary skill in view of the prior art and a *prima facie* case of obviousness has not been established for claims 34-40, 46, and 47 at least due to their dependence from allowable independent claim 29. Therefore, Applicant requests that the rejection of claims 34-40, 46, and 47 under 35 U.S.C. § 103(a) be withdrawn.

II. CONCLUSION

Applicant respectfully submits that claims 29-65 are in condition for allowance.

In view of the foregoing, Applicant respectfully requests reconsideration and reexamination of this application, and the timely allowance of the pending claims.

Please grant any extensions of time required to enter this response and charge any additional required fees to Deposit Account 06-0916.

Respectfully submitted,

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